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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,533	11/24/2003	Fukui Yoshihito	034071-001	1999

21839 7590 12/28/2006
BUCHANAN, INGERSOLL & ROONEY PC
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

PATEL, NATASHA

ART UNIT	PAPER NUMBER
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3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/718,533

Applicant(s)

YOSHIHITO, FUKUI

Examiner

Natasha N. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 12-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-11 is/are rejected.
- 7) ☒ Claim(s) 7-8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8 Feb. 2005
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species:

Species A: Figure 1

Species B: Figure 4

Species C: Figure 6

Species D: Figure 8

Species E: Figure 10

2. The species are independent or distinct because the different embodiments exemplified by Figures 1, 4, 6, 8, and 10 each have a different mode of operation.

3. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

4. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

6. During a telephone conversation with Matthew Schneider on December 7, 2006 a provisional election was made with traverse to prosecute the invention of Species A, claims 1-11. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

7. The disclosure is objected to because of the following informalities: priority benefits must be stated in the first sentence of the specification following the title, or in an application data sheet (see MPEP 201.11). Appropriate correction is required.

8. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f). The Examiner suggests changing the disclosure to incorporate the equivalent

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U.S. Patents disclosed by the Applicant on the Information Disclosure Statement submitted February 8, 2005.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 1 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kroll et al. (PG Pub. 2001/0049543).

11. Regarding Claim 1, Kroll discloses a heart treatment equipment comprising: a pulse generator (see ventricular pulse generator 72) for supplying a heart stimulation pulse to a first heart stimulating electrode (see tip electrode 32) provided in a right ventricle of the heart and for supplying a heart stimulation pulse to a second heart stimulating electrode (see tip electrode 26) provided in a left ventricle of the heart, and a controller (see microcontroller 60) for selecting one of or both of said right ventricle pulse generator and said left ventricle pulse generator (see par. 19 and 22), wherein said controller selects both of said right ventricle pulse generator and said left ventricle pulse generator when a heart rate exceeds a predetermined value (see par. 60). The examiner considers that a single pulse generator is equivalent to two separate pulse generators since the single pulse generator is capable of deciding when the generator should issue a RV pulse and when the generator should issue a LV pulse. Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention

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to make separate pulse generators for the RV and LV since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art (*Nerwin v. Erlichman*, 168 USPQ 177, 179). The examiner considers that simultaneous stimulation of both ventricles is the result of the controller selecting both ventricles because there are two leads—one for each ventricle; and both ventricles will not be stimulated unless the controller selects both leads.

12. Claims 2-4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (PG Pub. 2001/0049543) as applied to claim 1 above, and further in view of Weinberg et al. (2003/0078623).

13. Regarding Claim 2, Kroll does not disclose vagal stimulation. Weinberg discloses a similar biventricular pacing method in which vagal nerve stimulation is utilized. Weinberg discloses a nerve stimulator for supplying a nerve stimulation pulse to a nerve stimulation electrode, which stimulates a vagus nerve, wherein said nerve stimulator generates a nerve stimulation pulse when a heart rate exceeds a predetermined value (see par. 31 and 151). The examiner considers that a specific heart rate must be exceeded for the heart rate to be classified as a tachycardia. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize vagal stimulation into Kroll's invention because Weinberg teaches that vagal stimulation provides enhanced control over tachycardia therapy (see par. 31).

14. Regarding Claim 3, see rejection of similarly worded Claims 1 and 2 above. As to selecting the right and left ventricles in response to a timing of nerve stimulation, Weinberg discloses a single pass lead that can stimulate a desired portion of the right

vagus nerve and stimulate the right atrium, the right ventricle and/or the left ventricle (see par. 151). The examiner considers that if the vagal stimulation occurs at the same time as the left and right ventricles, then the vagal stimulation is occurring in response to the ventricular stimulation.

15. Regarding Claim 4, Weinberg discloses that the equipment further comprises an atrium event detector for detecting a spontaneous contraction of an atrium and atrioventricular delay time measuring portion responsive to said atrium event detector for measuring time after detecting the spontaneous contraction of the atrium (see par. 68). The examiner considers that if a timer is timing the AV delay, an atrial event had to have been detected otherwise the timer would not know when to start timing the delay. In other words, the AV delay inherently requires the detection of an atrial event.

16. Regarding Claim 9, see rejection of similarly worded Claim 1 above. The examiner considers that the simultaneous pacing of Kroll's device requires that the left and right ventricles be selected at the same time.

17. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (PG Pub. 2001/0049543) in view of Weinberg et al. (2003/0078623) as applied to Claim 3 above, and further in view of Vanhout (US Patent 6,842,642).

18. Regarding Claims 5 and 6, Weinberg discloses circuitry for setting the AV delay (see par. 68 and 80). Weinberg does not elaborate on the AV delays with respect to the ventricles selected for stimulation. Vanhout teaches that the AV delay should be shorter in the case of bi-ventricular pacing (see col. 6, lines 19-25). It would be obvious to one of ordinary skill in the art at the time of the invention to perform ventricular stimulation

when one of said right ventricle pulse generator and said left ventricle pulse generator is selected and said atrioventricular delay time measuring portion is at a first atrioventricular delay time; and a ventricle stimulation is performed when both of said right ventricle pulse generator and said left ventricle pulse generator are selected and said atrioventricular delay time measuring portion is at a second atrioventricular delay time, wherein said second atrioventricular delay time is shorter than said first atrioventricular delay time because Vanhout teaches that when two ventricles are being paced, it is preferable to have a shorter AV delay to prevent the ventricles from contracting autonomously (see col. 6, lines 19-25).

19. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (PG Pub. 2001/0049543) in view of Weinberg et al. (2003/0078623) as applied to Claim 3 above, and further in view of Turcott (US Patent 6,522,923).

20. Regarding Claims 10 and 11, Kroll does not elaborate on the order in which the ventricles are stimulated. Turcott discloses that said left ventricle pulse generator is operated for the ventricle stimulation subsequently to the operation of said right ventricle pulse generator after a predetermined time where both of said right ventricle pulse generator and said left ventricle pulse generator are selected. Turcott also discloses the other possibility, wherein said right ventricle pulse generator is operated for the ventricle stimulation subsequently to the operation of said left ventricle pulse generator after a predetermined time where both of said right ventricle pulse generator and said left ventricle pulse generator are selected (see col. 21, lines 25-29). It would have been obvious to one of ordinary skill in the art at the time of the invention to play around with

the pacing parameters in such a way because Turcott teaches that the various pacing parameters optimize cardiac performance (see Abstract).

Allowable Subject Matter

21. Claims 7 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

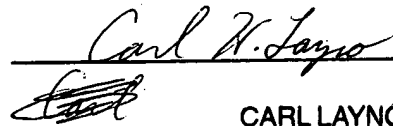
23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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24. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NNP
12/21/2006

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766


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